INSURANCE CODE

TITLE 8. HEALTH INSURANCE AND OTHER HEALTH COVERAGES

SUBTITLE E. BENEFITS PAYABLE UNDER HEALTH COVERAGES

CHAPTER 1369. BENEFITS RELATED TO PRESCRIPTION DRUGS AND DEVICES

AND RELATED SERVICES

SUBCHAPTER A. COVERAGE OF PRESCRIPTION DRUGS IN GENERAL

Sec. 1369.001. DEFINITIONS. In this subchapter:

- (1) "Contraindication" means the potential for, or the occurrence of:
- (A) an undesirable change in the therapeutic effect of a prescribed drug because of the presence of a disease condition in the patient for whom the drug is prescribed; or
- (B) a clinically significant adverse effect of a prescribed drug on a disease condition of the patient for whom the drug is prescribed.
- (2) "Drug" has the meaning assigned by Section 551.003, Occupations Code.
- (2-a) "Enrollee" means an individual who is covered under a health benefit plan, including a covered dependent.
- (3) "Indication" means a symptom, cause, or occurrence in a disease that points out the cause, diagnosis, course of treatment, or prognosis of the disease.
- (4) "Peer-reviewed medical literature" means scientific studies published in a peer-reviewed national professional journal.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005. Amended by:

Acts 2017, 85th Leg., R.S., Ch. 727 (S.B. 1076), Sec. 1, eff. September 1, 2017.

Sec. 1369.002. APPLICABILITY OF SUBCHAPTER. This subchapter applies only to a health benefit plan that provides benefits for medical or surgical expenses incurred as a result of a health condition, accident, or sickness, including an individual, group, blanket, or franchise insurance policy or insurance

agreement, a group hospital service contract, or an individual or group evidence of coverage or similar coverage document that is offered by:

- (1) an insurance company;
- (2) a group hospital service corporation operating under Chapter 842;
- (3) a fraternal benefit society operating under Chapter 885;
- (4) a stipulated premium company operating under Chapter 884;
 - (5) a reciprocal exchange operating under Chapter 942;
- (6) a health maintenance organization operating under Chapter 843;
- (7) a multiple employer welfare arrangement that holds a certificate of authority under Chapter 846; or
- (8) an approved nonprofit health corporation that holds a certificate of authority under Chapter 844.

 Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005.
- Sec. 1369.003. EXCEPTION. This subchapter does not apply to:
 - (1) a health benefit plan that provides coverage:
- (A) only for a specified disease or for another limited benefit;
 - (B) only for accidental death or dismemberment;
- (C) for wages or payments in lieu of wages for a period during which an employee is absent from work because of sickness or injury;
- (D) as a supplement to a liability insurance policy;
 - (E) for credit insurance;
 - (F) only for dental or vision care;
 - (G) only for hospital expenses; or
 - (H) only for indemnity for hospital confinement;
- (2) a small employer health benefit plan written under Chapter 1501;
 - (3) a Medicare supplemental policy as defined by

Section 1882(g)(1), Social Security Act (42 U.S.C. Section 1395ss), as amended;

- (4) a workers' compensation insurance policy;
- (5) medical payment insurance coverage provided under a motor vehicle insurance policy; or
- (6) a long-term care insurance policy, including a nursing home fixed indemnity policy, unless the commissioner determines that the policy provides benefit coverage so comprehensive that the policy is a health benefit plan as described by Section 1369.002.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005.

Sec. 1369.004. COVERAGE REQUIRED. (a) A health benefit plan that covers drugs must cover any drug prescribed to treat an enrollee for a chronic, disabling, or life-threatening illness covered under the plan if the drug:

- (1) has been approved by the United States Food and Drug Administration for at least one indication; and
- (2) is recognized by the following for treatment of the indication for which the drug is prescribed:
- (A) a prescription drug reference compendium approved by the commissioner for purposes of this section; or
- (B) substantially accepted peer-reviewed medical literature.
- (b) Coverage of a drug required under Subsection (a) must include coverage of medically necessary services associated with the administration of the drug.
- (c) A health benefit plan issuer may not, based on a "medical necessity" requirement, deny coverage of a drug required under Subsection (a) unless the reason for the denial is unrelated to the legal status of the drug use.
- (d) This section does not require a health benefit plan to cover:
- (1) experimental drugs that are not otherwise approved for an indication by the United States Food and Drug Administration;
 - (2) any disease or condition that is excluded from

coverage under the plan; or

(3) a drug that the United States Food and Drug Administration has determined to be contraindicated for treatment of the current indication.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005.

- Sec. 1369.0041. CERTAIN PAYMENTS AND REFILLS. (a) A health benefit plan issuer that covers prescription drugs may not require an enrollee to make a payment for a prescription drug at the point of sale in an amount greater than the lesser of:
 - (1) the applicable copayment;
- $\qquad \qquad \text{(2)} \quad \text{the allowable claim amount for the prescription} \\ \text{drug; or } \\$
- (3) the amount an individual would pay for the drug if the individual purchased the drug without using a health benefit plan or any other source of drug benefits or discounts.
- (b) A health benefit plan that covers prescription eye drops to treat a chronic eye disease or condition must allow the refill of prescription eye drops if the enrollee timely pays at the point of sale the maximum amount allowed by Subsection (a) and:
- (1) the original prescription states that additional quantities of the eye drops are needed;
- (2) the refill does not exceed the total quantity of dosage units authorized by the prescribing provider on the original prescription, including refills; and
- (3) the refill is dispensed on or before the last day of the prescribed dosage period and:
- (A) not earlier than the 21st day after the date a prescription for a 30-day supply of eye drops is dispensed;
- (B) not earlier than the 42nd day after the date a prescription for a 60-day supply of eye drops is dispensed; or
- (C) not earlier than the 63rd day after the date a prescription for a 90-day supply of eye drops is dispensed.

 Added by Acts 2017, 85th Leg., R.S., Ch. 727 (S.B. 1076), Sec. 2, eff. September 1, 2017.

Sec. 1369.005. RULES. The commissioner may adopt rules to

implement this subchapter.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005.

SUBCHAPTER B. COVERAGE OF PRESCRIPTION DRUGS SPECIFIED BY DRUG FORMULARY

Sec. 1369.051. DEFINITIONS. In this subchapter:

- (1) "Clinical practice guideline" means a statement systematically developed by a multidisciplinary panel of experts composed of physicians and, as necessary, other health care providers to assist a patient or health care provider in making a decision about appropriate health care for a specific clinical circumstance or condition.
- (1-a) "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols, and clinical practice guidelines used by a health benefit plan issuer, utilization review organization, or independent review organization to determine the medical necessity and appropriateness or the experimental or investigational nature of a health care service or prescription drug.
 - (1-b) "Drug formulary" means a list of drugs:
- (A) for which a health benefit plan provides coverage;
- (B) for which a health benefit plan issuer approves payment; or
- (C) that a health benefit plan issuer encourages or offers incentives for physicians to prescribe.
- (2) "Enrollee" means an individual who is covered under a health benefit plan, including a covered dependent.
- (3) "Physician" means a person licensed as a physician by the Texas State Board of Medical Examiners.
- (4) "Prescription drug" has the meaning assigned by Section 551.003, Occupations Code.
- (5) "Step therapy protocol" means a protocol that requires an enrollee to use a prescription drug or sequence of prescription drugs other than the drug that the enrollee's physician recommends for the enrollee's treatment before the health

benefit plan provides coverage for the recommended drug.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005.

Amended by:

Acts 2011, 82nd Leg., R.S., Ch. 501 (H.B. 1405), Sec. 1, eff. September 1, 2011.

Acts 2017, 85th Leg., R.S., Ch. 103 (S.B. 680), Sec. 1, eff. September 1, 2017.

Sec. 1369.052. APPLICABILITY OF SUBCHAPTER. This subchapter applies only to a health benefit plan that provides benefits for medical or surgical expenses incurred as a result of a health condition, accident, or sickness, including an individual, group, blanket, or franchise insurance policy or insurance agreement, a group hospital service contract, or a small or large employer group contract or similar coverage document that is offered by:

- (1) an insurance company;
- (2) a group hospital service corporation operating under Chapter 842;
- (3) a fraternal benefit society operating under Chapter 885;
- (4) a stipulated premium company operating under Chapter 884;
 - (5) a reciprocal exchange operating under Chapter 942;
- (6) a health maintenance organization operating under Chapter 843;
- (7) a multiple employer welfare arrangement that holds a certificate of authority under Chapter 846; or
- (8) an approved nonprofit health corporation that holds a certificate of authority under Chapter 844.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005. Amended by:

Acts 2011, 82nd Leg., R.S., Ch. 501 (H.B. 1405), Sec. 2, eff. September 1, 2011.

Sec. 1369.053. EXCEPTION. This subchapter does not apply to:

- (1) a health benefit plan that provides coverage:
- (A) only for a specified disease or for another single benefit;
 - (B) only for accidental death or dismemberment;
- (C) for wages or payments in lieu of wages for a period during which an employee is absent from work because of sickness or injury;
- (D) as a supplement to a liability insurance policy;
 - (E) for credit insurance;
 - (F) only for dental or vision care;
 - (G) only for hospital expenses; or
 - (H) only for indemnity for hospital confinement;
- (2) a Medicare supplemental policy as defined by Section 1882(g)(1), Social Security Act (42 U.S.C. Section 1395ss), as amended;
 - (3) a workers' compensation insurance policy;
- (4) medical payment insurance coverage provided under a motor vehicle insurance policy;
- (5) a long-term care insurance policy, including a nursing home fixed indemnity policy, unless the commissioner determines that the policy provides benefit coverage so comprehensive that the policy is a health benefit plan as described by Section 1369.052;
- (6) the child health plan program under Chapter 62, Health and Safety Code, or the health benefits plan for children under Chapter 63, Health and Safety Code; or
- (7) a Medicaid managed care program operated under Chapter 533, Government Code, or a Medicaid program operated under Chapter 32, Human Resources Code.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005. Amended by:

Acts 2011, 82nd Leg., R.S., Ch. 501 (H.B. 1405), Sec. 3, eff. September 1, 2011.

Sec. 1369.054. NOTICE AND DISCLOSURE OF CERTAIN INFORMATION REQUIRED. An issuer of a health benefit plan that covers

prescription drugs and uses one or more drug formularies to specify the prescription drugs covered under the plan shall:

- (1) provide in plain language in the coverage documentation provided to each enrollee:
- (A) notice that the plan uses one or more drug formularies;
 - (B) an explanation of what a drug formulary is;
- (C) a statement regarding the method the issuer uses to determine the prescription drugs to be included in or excluded from a drug formulary;
- (D) a statement of how often the issuer reviews the contents of each drug formulary; and
- (E) notice that an enrollee may contact the issuer to determine whether a specific drug is included in a particular drug formulary;
- (2) disclose to an individual on request, not later than the third business day after the date of the request, whether a specific drug is included in a particular drug formulary; and
- (3) notify an enrollee and any other individual who requests information under this section that the inclusion of a drug in a drug formulary does not guarantee that an enrollee's health care provider will prescribe that drug for a particular medical condition or mental illness.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005. Amended by:

Acts 2011, 82nd Leg., R.S., Ch. 501 (H.B. 1405), Sec. 4, eff. September 1, 2011.

Sec. 1369.0541. MODIFICATION OF DRUG COVERAGE UNDER PLAN.

- (a) A health benefit plan issuer may modify drug coverage provided under a health benefit plan if:
- (1) the modification occurs at the time of coverage renewal;
- (2) the modification is effective uniformly among all group health benefit plan sponsors covered by identical or substantially identical health benefit plans or all individuals covered by identical or substantially identical individual health

benefit plans, as applicable; and

- (3) not later than the 60th day before the date the modification is effective, the issuer provides written notice of the modification to the commissioner, each affected group health benefit plan sponsor, each affected enrollee in an affected group health benefit plan, and each affected individual health benefit plan holder.
- (b) Modifications affecting drug coverage that require notice under Subsection (a) include:
 - (1) removing a drug from a formulary;
- (2) adding a requirement that an enrollee receive prior authorization for a drug;
 - (3) imposing or altering a quantity limit for a drug;
- (4) imposing a step-therapy restriction for a drug; and
- (5) moving a drug to a higher cost-sharing tier unless a generic drug alternative to the drug is available.
- (c) A health benefit plan issuer may elect to offer an enrollee in the plan the option of receiving notifications required by this section by e-mail.

Added by Acts 2011, 82nd Leg., R.S., Ch. 501 (H.B. 1405), Sec. 5, eff. September 1, 2011.

- Sec. 1369.0545. STEP THERAPY PROTOCOLS. (a) A health benefit plan issuer that requires a step therapy protocol before providing coverage for a prescription drug must establish, implement, and administer the step therapy protocol in accordance with clinical review criteria readily available to the health care industry. The health benefit plan issuer shall take into account the needs of atypical patient populations and diagnoses in establishing the clinical review criteria. The clinical review criteria:
- (1) must consider generally accepted clinical practice guidelines that are:
- (A) developed and endorsed by a multidisciplinary panel of experts described by Subsection (b);
 - (B) based on high quality studies, research, and

medical practice;

- (C) created by an explicit and transparent process that:
- (i) minimizes bias and conflicts of interest;
- (ii) explains the relationship between
 treatment options and outcomes;
- (iii) rates the quality of the evidence supporting the recommendations; and
- (iv) considers relevant patient subgroups and preferences; and
- (D) updated at appropriate intervals after a review of new evidence, research, and treatments; or
- (2) if clinical practice guidelines described by Subdivision (1) are not reasonably available, may be based on peer-reviewed publications developed by independent experts, which may include physicians, with expertise applicable to the relevant health condition.
- (b) A multidisciplinary panel of experts composed of physicians and, as necessary, other health care providers that develops and endorses clinical practice guidelines under Subsection (a)(1) must manage conflicts of interest by:
- (1) requiring each member of the panel's writing or review group to:
- (A) disclose any potential conflict of interest, including a conflict of interest involving an insurer, health benefit plan issuer, or pharmaceutical manufacturer; and
- (B) recuse himself or herself in any situation in which the member has a conflict of interest;
- (2) using a methodologist to work with writing groups to provide objectivity in data analysis and the ranking of evidence by preparing evidence tables and facilitating consensus; and
- (3) offering an opportunity for public review and comment.
- (c) Subsection (b) does not apply to a panel or committee of experts, including a pharmacy and therapeutics committee, established by a health benefit plan issuer or a pharmacy benefit

manager that advises the health benefit plan issuer or pharmacy benefit manager regarding drugs or formularies.

Added by Acts 2017, 85th Leg., R.S., Ch. 103 (S.B. 680), Sec. 2, eff. September 1, 2017.

Sec. 1369.0546. STEP THERAPY PROTOCOL EXCEPTION REQUESTS.

a) A health benefit plan issuer shall establish a process in a

user-friendly format that is readily accessible to a patient and prescribing provider, in the health benefit plan's formulary document and otherwise, through which an exception request under

this section may be submitted by the provider.

(b) A prescribing provider on behalf of a patient may submit to the patient's health benefit plan issuer a written request for an exception to a step therapy protocol required by the patient's health benefit plan. The provider shall submit the request on the standard form prescribed by the commissioner under Section 1369.304.

- (c) A health benefit plan issuer shall grant a written request under Subsection (b) if the request includes the prescribing provider's written statement, with supporting documentation, stating that:
 - (1) the drug required under the step therapy protocol:
 - (A) is contraindicated;
- (B) will likely cause an adverse reaction in or physical or mental harm to the patient; or
- (C) is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen;
- (2) the patient previously discontinued taking the drug required under the step therapy protocol, or another prescription drug in the same pharmacologic class or with the same mechanism of action as the required drug, while under the health benefit plan currently in force or while covered under another health benefit plan because the drug was not effective or had a diminished effect or because of an adverse event;
- (3) the drug required under the step therapy protocol is not in the best interest of the patient, based on clinical

appropriateness, because the patient's use of the drug is expected to:

- (A) cause a significant barrier to the patient's adherence to or compliance with the patient's plan of care;
- (B) worsen a comorbid condition of the patient; or
- (C) decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; or
- (4)(A) the drug that is subject to the step therapy protocol was prescribed for the patient's condition;

(B) the patient:

(i) received benefits for the drug under the health benefit plan currently in force or a previous health benefit plan; and

(ii) is stable on the drug; and

- (C) the change in the patient's prescription drug regimen required by the step therapy protocol is expected to be ineffective or cause harm to the patient based on the known clinical characteristics of the patient and the known characteristics of the required prescription drug regimen.
- (d) Except as provided by Subsection (e), if a health benefit plan issuer does not deny an exception request described by Subsection (c) before 72 hours after the health benefit plan issuer receives the request, the request is considered granted.
- (e) If an exception request described by Subsection (c) also states that the prescribing provider reasonably believes that denial of the request makes the death of or serious harm to the patient probable, the request is considered granted if the health benefit plan issuer does not deny the request before 24 hours after the health benefit plan issuer receives the request.
- (f) The denial of an exception request under this section is an adverse determination for purposes of Section 4201.002 and is subject to appeal under Subchapters H and I, Chapter 4201.

 Added by Acts 2017, 85th Leg., R.S., Ch. 103 (S.B. 680), Sec. 2, eff. September 1, 2017.

Sec. 1369.055. CONTINUATION OF COVERAGE REQUIRED; OTHER DRUGS NOT PRECLUDED. (a) An issuer of a health benefit plan that covers prescription drugs shall offer to each enrollee at the contracted benefit level and until the enrollee's plan renewal date any prescription drug that was approved or covered under the plan for a medical condition or mental illness, regardless of whether the drug has been removed from the health benefit plan's drug formulary before the plan renewal date.

- (b) This section does not prohibit a physician or other health professional who is authorized to prescribe a drug from prescribing a drug that is an alternative to a drug for which continuation of coverage is required under Subsection (a) if the alternative drug is:
 - (1) covered under the health benefit plan; and
- (2) medically appropriate for the enrollee.

 Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005.

 Amended by:

Acts 2011, 82nd Leg., R.S., Ch. 501 (H.B. 1405), Sec. 6, eff. September 1, 2011.

Sec. 1369.056. ADVERSE DETERMINATION. (a) The refusal of a health benefit plan issuer to provide benefits to an enrollee for a prescription drug is an adverse determination for purposes of Section 4201.002 if:

- (1) the drug is not included in a drug formulary used by the health benefit plan; and
- (2) the enrollee's physician has determined that the drug is medically necessary.
- (b) The enrollee may appeal the adverse determination under Subchapters ${\tt H}$ and ${\tt I}$, Chapter 4201.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005. Amended by:

Acts 2007, 80th Leg., R.S., Ch. 730 (H.B. 2636), Sec. 2G.012, eff. April 1, 2009.

Acts 2011, 82nd Leg., R.S., Ch. 501 (H.B. 1405), Sec. 7, eff. September 1, 2011.

Sec. 1369.057. RULES. The commissioner may adopt rules to implement this subchapter.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005.

SUBCHAPTER B-1. TRANSPARENCY REQUIREMENTS FOR CERTAIN INDIVIDUAL HEALTH BENEFIT PLANS

Sec. 1369.076. DEFINITIONS. In this subchapter, terms defined by Subchapter B have the meanings assigned by that subchapter.

Added by Acts 2017, 85th Leg., R.S., Ch. 135 (H.B. 1227), Sec. 1, eff. September 1, 2017.

Sec. 1369.077. APPLICABILITY OF SUBCHAPTER. This subchapter applies only to an individual health benefit plan to which Subchapter B applies.

Added by Acts 2017, 85th Leg., R.S., Ch. 135 (H.B. 1227), Sec. 1, eff. September 1, 2017.

Sec. 1369.078. FORMULARY INFORMATION ON INTERNET WEBSITE.

(a) A health benefit plan issuer shall display on a public Internet website maintained by the issuer formulary information for each of the issuer's individual health benefit plans as required by the commissioner by rule.

(b) A direct electronic link to the formulary information must be displayed in a conspicuous manner in the electronic summary of benefits and coverage of each individual health benefit plan issued by the health benefit plan issuer on the health benefit plan issuer's Internet website. The information must be publicly accessible to enrollees, prospective enrollees, and others without necessity of providing a password, a user name, or personally identifiable information.

Added by Acts 2015, 84th Leg., R.S., Ch. 1038 (H.B. 1624), Sec. 1, eff. September 1, 2015.

Transferred, redesignated and amended from Insurance Code, Section 1369.0542 by Acts 2017, 85th Leg., R.S., Ch. 135 (H.B. 1227), Sec. 2, eff. September 1, 2017.

Sec. 1369.079. FORMULARY DISCLOSURE REQUIREMENTS. (a) The commissioner shall develop and adopt by rule requirements to promote consistency and clarity in the disclosure of formularies to facilitate comparison shopping among individual health benefit plans.

- (b) The requirements adopted under Subsection (a) must apply to each prescription drug:
- (1) included in a formulary and dispensed in a network pharmacy; or
- (2) covered under an individual health benefit plan and typically administered by a physician or health care provider.
 - (c) The formulary disclosures must:
 - (1) be electronically searchable by drug name;
- (2) include for each drug the information required by Subsection (d) in the order listed in that subsection; and
- (3) indicate each formulary that applies to each individual health benefit plan issued by the issuer.
 - (d) The formulary disclosures must include for each drug:
- (1) the cost-sharing amount for each drug, including as applicable:
 - (A) the dollar amount of a copayment; or
 - (B) for a drug subject to coinsurance:
- (i) an enrollee's cost-sharing amount
 stated in dollars; or
- (ii) a cost-sharing range, denoted as
 follows:
 - (a) under \$100 \$;
 - (b) \$100-\$250 \$\$;
 - (c) \$251-\$500 \$\$\$;
 - (d) \$501-\$1,000 \$\$\$; or
 - (e) over \$1,000 \$\$\$\$;
- (2) a disclosure of prior authorization, step therapy, or other protocol requirements for each drug;
- (3) if the individual health benefit plan uses a tier-based formulary, the specific tier for each drug listed in the formulary;

- (4) a description of how prescription drugs will specifically be included in or excluded from the deductible, including a description of out-of-pocket costs for a prescription drug that may not apply to the deductible;
 - (5) identification of preferred formulary drugs; and
 - (6) an explanation of coverage of each formulary drug.
- (e) The commissioner by rule may allow an alternative method of making disclosures required under Subsection (d)(1) relating to cost-sharing through a web-based tool that must:
- (1) be publicly accessible to enrollees, prospective enrollees, and others without necessity of providing a password, a user name, or personally identifiable information;
- (2) allow consumers to electronically search formulary information by the name under which the individual health benefit plan is marketed; and
- (3) be accessible through a direct link that is displayed on each page of the formulary disclosure that lists each drug as required under Subsection (c).

Added by Acts 2015, 84th Leg., R.S., Ch. 1038 (H.B. 1624), Sec. 1, eff. September 1, 2015.

Transferred, redesignated and amended from Insurance Code, Section 1369.0543 by Acts 2017, 85th Leg., R.S., Ch. 135 (H.B. 1227), Sec. 2, eff. September 1, 2017.

Sec. 1369.080. FORMULARY INFORMATION PROVIDED BY TOLL-FREE TELEPHONE NUMBER. In addition to providing the information described by Section 1369.079(d)(1) in the manner required by Section 1369.079, a health benefit plan issuer may make the information available to enrollees, prospective enrollees, and others through a toll-free telephone number that operates at least during normal business hours.

Added by Acts 2015, 84th Leg., R.S., Ch. 1038 (H.B. 1624), Sec. 1, eff. September 1, 2015.

Transferred, redesignated and amended from Insurance Code, Section 1369.0544 by Acts 2017, 85th Leg., R.S., Ch. 135 (H.B. 1227), Sec. 2, eff. September 1, 2017.

SUBCHAPTER C. COVERAGE OF PRESCRIPTION CONTRACEPTIVE DRUGS AND DEVICES AND RELATED SERVICES

Sec. 1369.101. DEFINITIONS. In this subchapter:

- (1) "Enrollee" means a person who is entitled to benefits under a health benefit plan.
- (2) "Outpatient contraceptive service" means a consultation, examination, procedure, or medical service that is provided on an outpatient basis and that is related to the use of a drug or device intended to prevent pregnancy.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005.

Sec. 1369.102. APPLICABILITY OF SUBCHAPTER. This subchapter applies only to a health benefit plan, including a small employer health benefit plan written under Chapter 1501, that provides benefits for medical or surgical expenses incurred as a result of a health condition, accident, or sickness, including an individual, group, blanket, or franchise insurance policy or insurance agreement, a group hospital service contract, or an individual or group evidence of coverage or similar coverage document that is offered by:

- (1) an insurance company;
- (2) a group hospital service corporation operating under Chapter 842;
- (3) a fraternal benefit society operating under Chapter 885;
- (4) a stipulated premium company operating under Chapter 884;
 - (5) a reciprocal exchange operating under Chapter 942;
- (6) a health maintenance organization operating under Chapter 843;
- (7) a multiple employer welfare arrangement that holds a certificate of authority under Chapter 846; or
- (8) an approved nonprofit health corporation that holds a certificate of authority under Chapter 844.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005.

Sec. 1369.103. EXCEPTION. This subchapter does not apply to:

- (1) a health benefit plan that provides coverage only:
- (A) for a specified disease or for another limited benefit other than for cancer;
 - (B) for accidental death or dismemberment;
- (C) for wages or payments in lieu of wages for a period during which an employee is absent from work because of sickness or injury;
- (D) as a supplement to a liability insurance policy;
 - (E) for credit insurance;
 - (F) for dental or vision care; or
 - (G) for indemnity for hospital confinement;
- (2) a Medicare supplemental policy as defined by Section 1882(g)(1), Social Security Act (42 U.S.C. Section 1395ss), as amended;
 - (3) a workers' compensation insurance policy;
- (4) medical payment insurance coverage provided under a motor vehicle insurance policy; or
- (5) a long-term care insurance policy, including a nursing home fixed indemnity policy, unless the commissioner determines that the policy provides benefit coverage so comprehensive that the policy is a health benefit plan as described by Section 1369.102.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005.

- Sec. 1369.104. EXCLUSION OR LIMITATION PROHIBITED. (a) A health benefit plan that provides benefits for prescription drugs or devices may not exclude or limit benefits to enrollees for:
- (1) a prescription contraceptive drug or device approved by the United States Food and Drug Administration; or
 - (2) an outpatient contraceptive service.
- (b) This section does not prohibit a limitation that applies to all prescription drugs or devices or all services for which benefits are provided under a health benefit plan.
 - (c) This section does not require a health benefit plan to

cover abortifacients or any other drug or device that terminates a pregnancy.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005.

Sec. 1369.105. CERTAIN COST-SHARING PROVISIONS PROHIBITED.

(a) A health benefit plan may not impose a deductible, copayment, coinsurance, or other cost-sharing provision applicable to benefits for prescription contraceptive drugs or devices unless the amount of the required cost-sharing is the same as or less than the amount of the required cost-sharing applicable to benefits for other prescription drugs or devices under the plan.

(b) A health benefit plan may not impose a deductible, copayment, coinsurance, or other cost-sharing provision applicable to benefits for outpatient contraceptive services unless the amount of the required cost-sharing is the same as or less than the amount of the required cost-sharing applicable to benefits for other outpatient services under the plan.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005.

Sec. 1369.106. CERTAIN WAITING PERIODS PROHIBITED. (a) A health benefit plan may not impose a waiting period applicable to benefits for prescription contraceptive drugs or devices unless the waiting period is the same as or shorter than any waiting period applicable to benefits for other prescription drugs or devices under the plan.

(b) A health benefit plan may not impose a waiting period applicable to benefits for outpatient contraceptive services unless the waiting period is the same as or shorter than any waiting period applicable to benefits for other outpatient services under the plan.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005.

Sec. 1369.107. PROHIBITED CONDUCT. A health benefit plan issuer may not:

(1) solely because of the applicant's or enrollee's use or potential use of a prescription contraceptive drug or device or an outpatient contraceptive service, deny:

- $\mbox{(A)} \quad \mbox{the eligibility of an applicant to enroll in } \\ \mbox{the plan;}$
- (B) the continued eligibility of an enrollee for coverage under the plan; or
- (C) the eligibility of an enrollee to renew coverage under the plan;
- (2) provide a monetary incentive to an applicant for enrollment or an enrollee to induce the applicant or enrollee to accept coverage that does not satisfy the requirements of this subchapter; or
- (3) reduce or limit a payment to a health care professional, or otherwise penalize the professional, because the professional prescribes a contraceptive drug or device or provides an outpatient contraceptive service.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005.

Sec. 1369.108. EXEMPTION FOR ENTITIES ASSOCIATED WITH RELIGIOUS ORGANIZATION. (a) This subchapter does not require a health benefit plan that is issued by an entity associated with a religious organization or any physician or health care provider providing medical or health care services under the plan to offer, recommend, offer advice concerning, pay for, provide, assist in, perform, arrange, or participate in providing or performing a medical or health care service that violates the religious convictions of the organization, unless the prescription contraceptive coverage is necessary to preserve the life or health of the enrollee.

- (b) An issuer of a health benefit plan that excludes or limits coverage for medical or health care services under this section shall state the exclusion or limitation in:
 - (1) the plan's coverage document;
 - (2) the plan's statement of benefits;
 - (3) plan brochures; and
- (4) other informational materials for the plan.

 Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005.

Sec. 1369.109. ENFORCEMENT. A health benefit plan issuer

that violates this subchapter is subject to the enforcement provisions of Subtitle B, Title 2.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005.

SUBCHAPTER D. PHARMACY BENEFIT CARDS

- Sec. 1369.151. APPLICABILITY OF SUBCHAPTER. (a) This subchapter applies only to a health benefit plan that provides benefits for medical or surgical expenses incurred as a result of a health condition, accident, or sickness, including an individual, group, blanket, or franchise insurance policy or insurance agreement, a group hospital service contract, or an individual or group evidence of coverage or similar coverage document that is offered by:
 - (1) an insurance company;
- (2) a group hospital service corporation operating under Chapter 842;
- (3) a fraternal benefit society operating under Chapter 885;
- (4) a stipulated premium company operating under Chapter 884;
 - (5) a reciprocal exchange operating under Chapter 942;
- (6) a health maintenance organization operating under Chapter 843;
- (7) a multiple employer welfare arrangement that holds a certificate of authority under Chapter 846; or
- (8) an approved nonprofit health corporation that holds a certificate of authority under Chapter 844.
- (b) Notwithstanding any other law, this subchapter applies to coverage under:
 - (1) the basic coverage plan under Chapter 1551;
 - (2) the basic plan under Chapter 1575;
 - (3) the primary care coverage plan under Chapter 1579;
 - (4) the basic coverage plan under Chapter 1601;
- (5) the child health plan program under Chapter 62, Health and Safety Code; and
 - (6) the medical assistance program under Chapter 32,

Human Resources Code.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005. Amended by:

Acts 2009, 81st Leg., R.S., Ch. 1117 (H.B. 1138), Sec. 1, eff. September 1, 2009.

Sec. 1369.152. EXCEPTION. This subchapter does not apply to:

- (1) a health benefit plan that provides coverage:
- (A) only for a specified disease or for another limited benefit;
 - (B) only for accidental death or dismemberment;
- (C) for wages or payments in lieu of wages for a period during which an employee is absent from work because of sickness or injury;
- (D) as a supplement to a liability insurance policy;
 - (E) for credit insurance;
 - (F) only for dental or vision care;
 - (G) only for hospital expenses; or
 - (H) only for indemnity for hospital confinement;
- (2) a small employer health benefit plan written under Chapter 1501;
- (3) a Medicare supplemental policy as defined by Section 1882(g)(1), Social Security Act (42 U.S.C. Section 1395ss);
 - (4) a workers' compensation insurance policy;
- (5) medical payment insurance coverage provided under a motor vehicle insurance policy; or
- (6) a long-term care insurance policy, including a nursing home fixed indemnity policy, unless the commissioner determines that the policy provides benefit coverage so comprehensive that the policy is a health benefit plan as described by Section 1369.151.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005.

Sec. 1369.153. INFORMATION REQUIRED ON IDENTIFICATION CARD.

(a) An issuer of a health benefit plan that provides pharmacy

benefits to enrollees shall include on the front of the identification card of each enrollee:

- (1) the name of the entity administering the pharmacy benefits if the entity is different from the health benefit plan issuer;
 - (2) the group number applicable to the enrollee;
- (3) the identification number of the enrollee, which may not be the enrollee's social security number;
- (4) the bank identification number necessary for electronic billing;
- (5) the effective date of the coverage evidenced by the card; and
- (6) copayment information for generic and brand-name prescription drugs.
- (b) In addition to the information required under Subsection (a), the issuer of a health benefit plan shall include on the identification card of each enrollee:
- (1) the logo of the entity administering the pharmacy benefits if the entity is different from the health benefit plan issuer; and
- (2) a telephone number for contacting an appropriate person to obtain information relating to the pharmacy benefits provided under the plan.
- (c) In addition to complying with Subsections (a) and (b), an issuer of a health benefit plan may provide the information required under Subsections (a) and (b) in electronically readable form on the back of the identification card.
- (d) This section does not require a health benefit plan issuer that administers its own pharmacy benefits to issue an identification card separate from any identification card issued to an enrollee to evidence coverage under the plan if the identification card issued to evidence coverage contains the information required by Subsections (a) and (b).

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005. Amended by:

Acts 2009, 81st Leg., R.S., Ch. 1117 (H.B. 1138), Sec. 2, eff. September 1, 2009.

- Sec. 1369.154. RULES. (a) The commissioner shall adopt rules as necessary to implement this subchapter.
- (b) Rules adopted by the commissioner must be consistent with national standards established by the Workgroup for Electronic Data Interchange or by other similar organizations recognized by the commissioner.

Added by Acts 2003, 78th Leg., ch. 1274, Sec. 3, eff. April 1, 2005. Amended by:

Acts 2009, 81st Leg., R.S., Ch. 1117 (H.B. 1138), Sec. 3, eff. September 1, 2009.

SUBCHAPTER E. COVERAGE FOR ORALLY ADMINISTERED ANTICANCER MEDICATIONS

Sec. 1369.201. DEFINITIONS. In this subchapter:

- (1) "Health benefit exchange" means an American Health Benefit Exchange administered by the federal government or created pursuant to Section 1311(b), Patient Protection and Affordable Care Act (42 U.S.C. Section 18031).
- (2) "Qualified health plan" has the meaning assigned by Section 1301(a), Patient Protection and Affordable Care Act (42 U.S.C. Section 18021).

Added by Acts 2011, 82nd Leg., R.S., Ch. 105 (H.B. 438), Sec. 1, eff. September 1, 2011.

- Sec. 1369.202. APPLICABILITY OF SUBCHAPTER. This subchapter applies only to a health benefit plan, including a small employer health benefit plan written under Chapter 1501 or coverage provided by a health group cooperative under Subchapter B of that chapter, that provides benefits for medical or surgical expenses incurred as a result of a health condition, accident, or sickness, including an individual, group, blanket, or franchise insurance policy or insurance agreement, a group hospital service contract, or an individual or group evidence of coverage or similar coverage document that is offered by:
 - (1) an insurance company;

- (2) a group hospital service corporation operating under Chapter 842;
- (3) a fraternal benefit society operating under Chapter 885;
- (4) a stipulated premium company operating under Chapter 884;
 - (5) an exchange operating under Chapter 942;
 - (6) a Lloyd's plan operating under Chapter 941;
- $\qquad \qquad \text{(7)} \quad \text{a health maintenance organization operating under}$ Chapter 843; or
- (8) an approved nonprofit health corporation that holds a certificate of authority under Chapter 844.

 Added by Acts 2011, 82nd Leg., R.S., Ch. 105 (H.B. 438), Sec. 1, eff. September 1, 2011.
- Sec. 1369.203. EXCEPTION. (a) This subchapter does not apply to:
 - (1) a plan that provides coverage:
- (A) only for fixed indemnity benefits for a specified disease or diseases;
 - (B) only for accidental death or dismemberment;
- (C) for wages or payments in lieu of wages for a period during which an employee is absent from work because of sickness or injury;
- (D) as a supplement to a liability insurance policy;
 - (E) only for dental or vision care; or
 - (F) only for indemnity for hospital confinement;
- (2) a Medicare supplemental policy as defined by Section 1882(g)(1), Social Security Act (42 U.S.C. Section 1395ss);
 - (3) a workers' compensation insurance policy;
- (4) medical payment insurance coverage provided under an automobile insurance policy;
 - (5) a credit insurance policy;
- (6) a limited benefit policy that does not provide coverage for physical examinations or wellness exams;
 - (7) a multiple employer welfare arrangement that holds

a certificate of authority under Chapter 846; or

- (8) a long-term care insurance policy, including a nursing home fixed indemnity policy, unless the commissioner determines that the policy provides benefit coverage so comprehensive that the policy is a health benefit plan as described by Section 1369.201.
- (b) This subchapter does not apply to a qualified health plan offered through a health benefit exchange.

 Added by Acts 2011, 82nd Leg., R.S., Ch. 105 (H.B. 438), Sec. 1, eff. September 1, 2011.
- Sec. 1369.204. REQUIRED COVERAGE FOR ORALLY ADMINISTERED ANTICANCER MEDICATIONS. (a) A health benefit plan that provides coverage for cancer treatment must provide coverage for a prescribed, orally administered anticancer medication that is used to kill or slow the growth of cancerous cells on a basis no less favorable than intravenously administered or injected cancer medications that are covered as medical benefits by the plan.
- (b) This section does not prohibit a health benefit plan from requiring prior authorization for an orally administered anticancer medication. If an orally administered anticancer medication is authorized, the cost to the covered individual may not exceed the coinsurance or copayment that would be applied to a chemotherapy or other cancer treatment visit.
- (c) A health benefit plan issuer may not reclassify anticancer medications or increase a coinsurance, copayment, deductible, or other out-of-pocket expense imposed on anticancer medications to achieve compliance with this section. Any plan change that otherwise increases an out-of-pocket expense applied to anticancer medications must also be applied to the majority of comparable medical or pharmaceutical benefits under the plan.
- (d) This section does not prohibit a health benefit plan issuer from increasing cost-sharing for all benefits, including anticancer treatments.

Added by Acts 2011, 82nd Leg., R.S., Ch. 105 (H.B. 438), Sec. 1, eff. September 1, 2011.

SUBCHAPTER E-1. COVERAGE OF PRESCRIPTION DRUGS FOR STAGE-FOUR ADVANCED, METASTATIC CANCER

Sec. 1369.211. DEFINITIONS. In this subchapter:

- (1) "Associated conditions" means the symptoms or side effects associated with stage-four advanced, metastatic cancer or its treatment and which, in the judgment of the health care practitioner, further jeopardize the health of a patient if left untreated.
- (2) "Stage-four advanced, metastatic cancer" means cancer that has spread from the primary or original site of the cancer to nearby tissues, lymph nodes, or other areas or parts of the body.

Added by Acts 2019, 86th Leg., R.S., Ch. 1350 (H.B. 1584), Sec. 1, eff. September 1, 2019.

Sec. 1369.212. APPLICABILITY OF SUBCHAPTER. (a) This subchapter applies only to a health benefit plan that provides benefits for medical or surgical expenses or pharmacy benefits incurred as a result of a health condition, accident, or sickness, including an individual, group, blanket, or franchise insurance policy or insurance agreement, a group hospital service contract, or an individual or group evidence of coverage or similar coverage document that is issued by:

- (1) an insurance company;
- (2) a group hospital service corporation operating under Chapter 842;
- (3) a health maintenance organization operating under Chapter 843;
- (4) an approved nonprofit health corporation that holds a certificate of authority under Chapter 844;
- (5) a multiple employer welfare arrangement that holds a certificate of authority under Chapter 846;
- (6) a stipulated premium company operating under Chapter 884;
- (7) a fraternal benefit society operating under Chapter 885;

- (8) a Lloyd's plan operating under Chapter 941; or
- (9) an exchange operating under Chapter 942.
- (b) Notwithstanding any other law, this subchapter applies to:
- (1) a small employer health benefit plan subject to Chapter 1501, including coverage provided through a health group cooperative under Subchapter B of that chapter;
- (2) a standard health benefit plan issued under Chapter 1507;
 - (3) a basic coverage plan under Chapter 1551;
 - (4) a basic plan under Chapter 1575;
 - (5) a primary care coverage plan under Chapter 1579;
- (6) a plan providing basic coverage under Chapter 1601;
- (7) health benefits provided by or through a church benefits board under Subchapter I, Chapter 22, Business Organizations Code;
- (8) group health coverage made available by a school district in accordance with Section 22.004, Education Code;
- (9) the state Medicaid program, including the Medicaid managed care program operated under Chapter 533, Government Code;
- (10) the child health plan program under Chapter 62, Health and Safety Code;
- (11) a regional or local health care program operated under Section 75.104, Health and Safety Code; and
- (12) a self-funded health benefit plan sponsored by a professional employer organization under Chapter 91, Labor Code.
- (c) This subchapter applies to coverage under a group health benefit plan provided to a resident of this state regardless of whether the group policy, agreement, or contract is delivered, issued for delivery, or renewed in this state.

Added by Acts 2019, 86th Leg., R.S., Ch. 1350 (H.B. 1584), Sec. 1, eff. September 1, 2019.

Sec. 1369.213. PROHIBITED CONDUCT. (a) A health benefit plan that provides coverage for stage-four advanced, metastatic cancer and associated conditions may not require, before the health

benefit plan provides coverage of a prescription drug approved by the United States Food and Drug Administration, that the enrollee:

- (1) fail to successfully respond to a different drug;
 - (2) prove a history of failure of a different drug.
 - (b) This section applies only to a drug the use of which is:
- (1) consistent with best practices for the treatment of stage-four advanced, metastatic cancer or an associated condition;
- (2) supported by peer-reviewed, evidence-based literature; and
- (3) approved by the United States Food and Drug Administration.

Added by Acts 2019, 86th Leg., R.S., Ch. 1350 (H.B. 1584), Sec. 1, eff. September 1, 2019.

SUBCHAPTER F. AUDITS OF PHARMACISTS AND PHARMACIES

Sec. 1369.251. DEFINITIONS. In this subchapter:

- (1) "Desk audit" means an audit conducted by a health benefit plan issuer or pharmacy benefit manager at a location other than the location of the pharmacist or pharmacy. The term includes an audit performed at the offices of the plan issuer or pharmacy benefit manager during which the pharmacist or pharmacy provides requested documents for review by hard copy or by microfiche, disk, or other electronic media. The term does not include a review conducted not later than the third business day after the date a claim is adjudicated provided recoupment is not demanded.
- (2) "Extrapolation" means a mathematical process or technique used by a health benefit plan issuer or pharmacy benefit manager that administers pharmacy claims for a health benefit plan issuer in the audit of a pharmacy or pharmacist to estimate audit results or findings for a larger batch or group of claims not reviewed by the plan issuer or pharmacy benefit manager.
- (3) "Health benefit plan" means a plan that provides benefits for medical, surgical, or other treatment expenses incurred as a result of a health condition, a mental health

condition, an accident, sickness, or substance abuse, including:

- (A) an individual, group, blanket, or franchise insurance policy or insurance agreement, a group hospital service contract, or an individual or group evidence of coverage or similar coverage document that is issued by:
 - (i) an insurance company;
- (ii) a group hospital service corporation operating under Chapter 842;
- (iii) a health maintenance organization operating under Chapter 843;
- (iv) an approved nonprofit health corporation that holds a certificate of authority under Chapter 844;
- (v) a multiple employer welfare arrangement that holds a certificate of authority under Chapter 846;
- (vi) a stipulated premium company operating
 under Chapter 884;
- (vii) a fraternal benefit society operating
 under Chapter 885;
- (viii) a Lloyd's plan operating under Chapter 941; or
- (ix) an exchange operating under Chapter 942;
- (B) a small employer health benefit plan written under Chapter 1501; or
- (C) a health benefit plan issued under Chapter 1551, 1575, 1579, or 1601.
- (4) "On-site audit" means an audit that is conducted at:
- $\hbox{(A) the location of the pharmacist or pharmacy;}\\$ or
- $\begin{tabular}{ll} \textbf{(B)} & \textbf{another location at which the records under} \\ \textbf{review are stored.} \end{tabular}$
- (5) "Pharmacy benefit manager" has the meaning assigned by Section 4151.151.
- Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.

- Sec. 1369.252. EXCEPTIONS TO APPLICABILITY OF SUBCHAPTER. This subchapter does not apply to an issuer or provider of health benefits under or a pharmacy benefit manager administering pharmacy benefits under:
 - (1) the state Medicaid program;
 - (2) the federal Medicare program;
- (3) the state child health plan or health benefits plan for children under Chapter 62 or 63, Health and Safety Code;
 - (4) the TRICARE military health system;
- (5) a workers' compensation insurance policy or other form of providing medical benefits under Title 5, Labor Code; or
- (6) a self-funded health benefit plan as defined by the Employee Retirement Income Security Act of 1974 (29 U.S.C. Section 1001 et seq.).

Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.

Sec. 1369.253. CONFLICT WITH OTHER LAWS. If there is a conflict between this subchapter and a provision of Chapter 843 or 1301 related to a pharmacy benefit manager, this subchapter prevails.

Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.

Sec. 1369.254. AUDIT OF PHARMACIST OR PHARMACY; NOTICE; GENERAL PROVISIONS. (a) Except as provided by Subsection (d), a health benefit plan issuer or pharmacy benefit manager that performs an on-site audit under this subchapter of a pharmacist or pharmacy shall provide the pharmacist or pharmacy reasonable notice of the audit and accommodate the pharmacist's or pharmacy's schedule to the greatest extent possible. The notice required under this subsection must be in writing and must be sent by a means that allows tracking of delivery to the pharmacist or pharmacy not later than the 14th day before the date on which the on-site audit is scheduled to occur.

(b) Not later than the seventh day after the date a

pharmacist or pharmacy receives notice under Subsection (a), the pharmacist or pharmacy may request that an on-site audit be rescheduled to a mutually convenient date. The request must be reasonably granted.

- (c) Unless the pharmacist or pharmacy consents in writing, a health benefit plan issuer or pharmacy benefit manager may not schedule or have an on-site audit conducted:
- (1) except as provided by Subsection (d), before the 14th day after the date the pharmacist or pharmacy receives notice under Subsection (a), if applicable;
- (2) more than twice annually in connection with a particular payor; or
- $\hbox{ (3)} \quad \hbox{during the first five calendar days of January and } \\$ December.
- (d) A health benefit plan issuer or pharmacy benefit manager is not required to provide notice before conducting an audit if, after reviewing claims data, written or oral statements of pharmacy staff, wholesalers, or others, or other investigative information, including patient referrals, anonymous reports, or postings on Internet websites, the plan issuer or pharmacy benefit manager suspects the pharmacist or pharmacy subject to the audit committed fraud or made an intentional misrepresentation related to the pharmacy business. The pharmacist or pharmacy may not request that the audit be rescheduled under Subsection (b).
- (e) A pharmacist or pharmacy may be required to submit documents in response to a desk audit not earlier than the 20th day after the date the health benefit plan issuer or pharmacy benefit manager requests the documents.
- (f) A contract between a pharmacist or pharmacy and a health benefit plan issuer or pharmacy benefit manager must state detailed audit procedures. If a health benefit plan issuer or pharmacy benefit manager proposes a change to the audit procedures for an on-site audit or a desk audit, the plan issuer or pharmacy benefit manager must notify the pharmacist or pharmacy in writing of a change in an audit procedure not later than the 60th day before the effective date of the change.
 - (g) The list of the claims subject to an on-site audit must

be provided in the notice under Subsection (a) to the pharmacist or pharmacy and must identify the claims only by the prescription numbers or a date range for prescriptions subject to the audit. The last two digits of the prescription numbers provided may be omitted.

(h) If the health benefit plan issuer or pharmacy benefit manager in an on-site audit or a desk audit applies random sampling procedures to select claims for audit, the sample size may not be greater than 300 individual prescription claims.

Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.

Sec. 1369.255. COMPLETION OF AUDIT. An audit of a claim under Section 1369.254 must be completed on or before the one-year anniversary of the date the claim is received by the health benefit plan issuer or pharmacy benefit manager.

Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.

Sec. 1369.256. AUDIT REQUIRING PROFESSIONAL JUDGMENT. A health benefit plan issuer or pharmacy benefit manager that conducts an on-site audit or a desk audit involving a pharmacist's clinical or professional judgment must conduct the audit in consultation with a licensed pharmacist.

Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.

Sec. 1369.257. ACCESS TO PHARMACY AREA. A health benefit plan issuer or pharmacy benefit manager that conducts an on-site audit may not enter the pharmacy area unless escorted by an individual authorized by the pharmacist or pharmacy.

Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.

- Sec. 1369.258. VALIDATION USING CERTAIN RECORDS AUTHORIZED. A pharmacist or pharmacy that is being audited may:
 - (1) validate a prescription, refill of a prescription,

or change in a prescription with a prescription that complies with applicable federal laws and regulations and state laws and rules adopted under Section 554.051, Occupations Code; and

(2) validate the delivery of a prescription with a written record of a hospital, physician, or other authorized practitioner of the healing arts.

Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.

- Sec. 1369.2581. AUDIT DISCREPANCIES; WHOLESALE INVOICES.

 (a) A health benefit plan issuer or pharmacy benefit manager that audits wholesale invoices during an audit of a pharmacist or pharmacy may not audit the pharmacy claims of another health benefit plan or pharmacy benefit manager.
- (b) A health benefit plan issuer or pharmacy benefit manager shall reverse a finding of a discrepancy if:
- (1) the National Drug Code for the dispensed drug is in a quantity that is a subunit or multiple of the drug purchased by the pharmacist or pharmacy as supported by a wholesale invoice;
- (2) the pharmacist or pharmacy dispensed the correct quantity of the drug according to the prescription; and
- (3) the drug dispensed by the pharmacist or pharmacy shares all but the last two digits of the National Drug Code of the drug reflected on the supplier invoice.
- (c) A health benefit plan issuer or pharmacy benefit manager must accept as evidence to support the validity of a pharmacy claim related to a dispensed drug:
- (1) subject to validation, including validation by pharmacy purchase order and payment of a supplier invoice, copies of supplier invoices in the pharmacist's or pharmacy's possession, including:
- (A) supplier invoices issued before the date the drug was dispensed and not earlier than 60 days before the first day of the audit period; and
- (B) invoices and any supporting documents from any supplier authorized by federal or state law to transfer ownership of the drug acquired by the pharmacist or pharmacy; and

- (2) reports required by any state board or agency.
- (d) A health benefit plan issuer or pharmacy benefit manager must provide, not later than the fifth business day after the date of a request by the pharmacist or pharmacy, any supporting documents the pharmacist's or pharmacy's suppliers provided to the health benefit plan issuer or pharmacy benefit manager.

Added by Acts 2019, 86th Leg., R.S., Ch. 481 (H.B. 1455), Sec. 1, eff. September 1, 2019.

- Sec. 1369.259. CALCULATION OF RECOUPMENT; USE OF EXTRAPOLATION PROHIBITED. (a) A health benefit plan issuer or pharmacy benefit manager may not calculate the amount of a recoupment based on:
- (1) an absence of documentation the pharmacist or pharmacy is not required by applicable federal laws and regulations and state laws and rules to maintain; or
- (2) an error that does not result in actual financial harm to the patient or enrollee, the health benefit plan issuer, or the pharmacy benefit manager.
- (b) A health benefit plan issuer or pharmacy benefit manager may not require extrapolation audits as a condition of participation in a contract, network, or program for a pharmacist or pharmacy.
- (c) A health benefit plan issuer or pharmacy benefit manager may not use extrapolation to complete an on-site audit or a desk audit of a pharmacist or pharmacy. Notwithstanding Subsection (a)(2), the amount of a recoupment must be based on the actual overpayment or underpayment and may not be based on an extrapolation.
- (d) A health benefit plan issuer or pharmacy benefit manager may not include a dispensing fee amount in the calculation of an overpayment unless:
 - (1) the fee was a duplicate charge;
 - (2) the prescription for which the fee was charged:
 - (A) was not dispensed; or
 - (B) was dispensed:
 - (i) without the prescriber's authorization;

- (ii) to the wrong patient; or
- (iii) with the wrong instructions; or
- (3) the wrong drug was dispensed.

 Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.
- Sec. 1369.260. CLERICAL OR RECORDKEEPING ERROR; FRAUD ALLEGATION. (a) An unintentional clerical or recordkeeping error, such as a typographical error, scrivener's error, or computer error, found during an on-site audit or a desk audit:
- (1) is not prima facie evidence of fraud or intentional misrepresentation; and
- (2) may not be the basis of a recoupment unless the error results in actual financial harm to a patient or enrollee, health benefit plan issuer, or pharmacy benefit manager.
- (b) If the health benefit plan issuer or pharmacy benefit manager alleges that the pharmacist or pharmacy committed fraud or intentional misrepresentation described by Subsection (a), the health benefit plan issuer or pharmacy benefit manager must state the allegation in the final audit report required by Section 1369.264.
- (c) After an audit is initiated, a pharmacist or pharmacy may resubmit a claim described by Subsection (a) if the deadline for submission of a claim under Section 843.337 or 1301.102 has not expired.

Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.

- Sec. 1369.261. ACCESS TO PREVIOUS AUDIT REPORTS; UNIFORM AUDIT STANDARDS. (a) Except as provided by Subsection (b), a health benefit plan issuer or pharmacy benefit manager may have access to an audit report of a pharmacist or pharmacy only if the report was prepared in connection with an audit conducted by the health benefit plan issuer or pharmacy benefit manager.
- (b) A health benefit plan issuer or pharmacy benefit manager may have access to audit reports other than the reports described by Subsection (a) if, after reviewing claims data, written or oral

statements of pharmacy staff, wholesalers, or others, or other investigative information, including patient referrals, anonymous reports, or postings on Internet websites, the plan issuer or the pharmacy benefit manager suspects the audited pharmacist or pharmacy committed fraud or made an intentional misrepresentation related to the pharmacy business.

(c) An auditor must conduct an on-site audit or a desk audit of similarly situated pharmacists or pharmacies under the same audit standards.

Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.

Sec. 1369.262. COMPENSATION OF AUDITOR. An individual performing an on-site audit or a desk audit may not directly or indirectly receive compensation based on a percentage of the amount recovered as a result of the audit.

Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.

- Sec. 1369.263. CONCLUSION OF AUDIT; SUMMARY; PRELIMINARY AUDIT REPORT. (a) At the conclusion of an on-site audit or a desk audit, the health benefit plan issuer or pharmacy benefit manager shall:
- (1) provide to the pharmacist or pharmacy a summary of the audit findings; and
- (2) allow the pharmacist or pharmacy to respond to questions and alleged discrepancies, if any, and comment on and clarify the findings.
- (b) Not later than the 60th day after the date the audit is concluded, the health benefit plan issuer or pharmacy benefit manager shall send by a means that allows tracking of delivery to the pharmacist or pharmacy a preliminary audit report stating the results of the audit and a list identifying documentation, if any, required to resolve discrepancies, if any, found as a result of the audit.
- (c) The pharmacist or pharmacy may, by providing documentation or otherwise, challenge a result or remedy a

discrepancy stated in the preliminary audit report not later than the 30th day after the date the pharmacist or pharmacy receives the report.

- (d) The pharmacist or pharmacy may request an extension to provide documentation supporting a challenge. The request shall be reasonably granted. A health benefit plan issuer or pharmacy benefit manager that grants an extension is not subject to the deadline to send the final audit report under Section 1369.264.

 Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.
- Sec. 1369.264. FINAL AUDIT REPORT. Not later than the 120th day after the date the pharmacist or pharmacy receives a preliminary audit report under Section 1369.263, the health benefit plan issuer or pharmacy benefit manager shall send by a means that allows tracking of delivery to the pharmacist or pharmacy a final audit report that states:
- (1) the audit results after review of the documentation submitted by the pharmacist or pharmacy in response to the preliminary audit report; and
- (2) the audit results, including a description of all alleged discrepancies and explanations for and the amount of recoupments claimed after consideration of the pharmacist's or pharmacy's response to the preliminary audit report.

Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.

Sec. 1369.265. CERTAIN AUDITS EXEMPT FROM DEADLINES. A health benefit plan issuer or pharmacy benefit manager is not subject to the deadlines for sending a report under Sections 1369.263 and 1369.264 if, after reviewing claims data, written or oral statements of pharmacy staff, wholesalers, or others, or other investigative information, including patient referrals, anonymous reports, or postings on Internet websites, the plan issuer or pharmacy benefit manager suspects the audited pharmacist or pharmacy committed fraud or made an intentional misrepresentation related to the pharmacy business.

Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.

Sec. 1369.266. RECOUPMENT AND INTEREST CHARGED AFTER AUDIT.

(a) If an audit under this subchapter is conducted, the health benefit plan issuer or pharmacy benefit manager:

- (1) may recoup from the pharmacist or pharmacy an amount based only on a final audit report; and
- (2) may not accrue or assess interest on an amount due until the date the pharmacist or pharmacy receives the final audit report under Section 1369.264.
- (b) The limitations on recoupment and interest accrual or assessment under Subsection (a) do not apply to a health benefit plan issuer or pharmacy benefit manager that, after reviewing claims data, written or oral statements of pharmacy staff, wholesalers, or others, or other investigative information, including patient referrals, anonymous reports, or postings on Internet websites, suspects the audited pharmacist or pharmacy committed fraud or made an intentional misrepresentation related to the pharmacy business.

Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.

Sec. 1369.267. WAIVER PROHIBITED. The provisions of this subchapter may not be waived, voided, or nullified by contract.

Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.

Sec. 1369.268. REMEDIES NOT EXCLUSIVE. This subchapter may not be construed to waive a remedy at law available to a pharmacist or pharmacy.

Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.

Sec. 1369.269. ENFORCEMENT; RULES. The commissioner may enforce this subchapter and adopt and enforce reasonable rules necessary to accomplish the purposes of this subchapter.

Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.

Sec. 1369.270. LEGISLATIVE DECLARATION. Except as provided by Section 1369.252, it is the intent of the legislature that the requirements contained in this subchapter regarding the audit of claims to providers who are pharmacists or pharmacies apply to all health benefit plan issuers and pharmacy benefit managers unless otherwise prohibited by federal law.

Added by Acts 2013, 83rd Leg., R.S., Ch. 915 (H.B. 1358), Sec. 1, eff. September 1, 2013.

SUBCHAPTER G. STANDARD REQUEST FORM FOR PRIOR AUTHORIZATION OF PRESCRIPTION DRUG BENEFITS

Sec. 1369.301. DEFINITION. In this subchapter, "prescription drug" has the meaning assigned by Section 551.003, Occupations Code.

Added by Acts 2013, 83rd Leg., R.S., Ch. 1328 (S.B. 644), Sec. 1, eff. September 1, 2013.

Redesignated from Insurance Code, Section 1369.251 by Acts 2015, 84th Leg., R.S., Ch. 1236 (S.B. 1296), Sec. 21.001(38), eff. September 1, 2015.

Sec. 1369.302. APPLICABILITY OF SUBCHAPTER. (a) This subchapter applies only to a health benefit plan that provides benefits for medical or surgical expenses incurred as a result of a health condition, accident, or sickness, including an individual, group, blanket, or franchise insurance policy or insurance agreement, a group hospital service contract, or a small or large employer group contract or similar coverage document that is offered by:

- (1) an insurance company;
- (2) a group hospital service corporation operating under Chapter 842;
- (3) a fraternal benefit society operating under Chapter 885;

- (4) a stipulated premium company operating under Chapter 884;
 - (5) a reciprocal exchange operating under Chapter 942;
- (6) a health maintenance organization operating under Chapter 843;
- (7) a multiple employer welfare arrangement that holds a certificate of authority under Chapter 846; or
- (8) an approved nonprofit health corporation that holds a certificate of authority under Chapter 844.
- (b) This subchapter applies to group health coverage made available by a school district in accordance with Section 22.004, Education Code.
- (c) Notwithstanding any provision in Chapter 1551, 1575, 1579, or 1601 or any other law, this subchapter applies to:
 - (1) a basic coverage plan under Chapter 1551;
 - (2) a basic plan under Chapter 1575;
- (3) a primary care coverage plan under Chapter 1579; and
 - (4) basic coverage under Chapter 1601.
- (d) Notwithstanding any other law, this subchapter applies to coverage under:
- (1) the child health plan program under Chapter 62, Health and Safety Code, or the health benefits plan for children under Chapter 63, Health and Safety Code; and
- (2) the medical assistance program under Chapter 32, Human Resources Code.

Added by Acts 2013, 83rd Leg., R.S., Ch. 1328 (S.B. 644), Sec. 1, eff. September 1, 2013.

Redesignated from Insurance Code, Section 1369.252 by Acts 2015, 84th Leg., R.S., Ch. 1236 (S.B. 1296), Sec. 21.001(38), eff. September 1, 2015.

Sec. 1369.303. EXCEPTION. This subchapter does not apply to:

- (1) a health benefit plan that provides coverage:
- (A) only for a specified disease or for another single benefit;

- (B) only for accidental death or dismemberment;
- (C) for wages or payments in lieu of wages for a period during which an employee is absent from work because of sickness or injury;
- (D) as a supplement to a liability insurance policy;
 - (E) for credit insurance;
 - (F) only for dental or vision care;
 - (G) only for hospital expenses; or
 - (H) only for indemnity for hospital confinement;
- (2) a Medicare supplemental policy as defined by Section 1882(g)(1), Social Security Act (42 U.S.C. Section 1395ss);
- (3) medical payment insurance coverage provided under a motor vehicle insurance policy;
- (4) a long-term care insurance policy, including a nursing home fixed indemnity policy, unless the commissioner determines that the policy provides benefit coverage so comprehensive that the policy is a health benefit plan as described by Section 1369.302;
- (5) health and accident coverage provided by a risk pool created under Chapter 172, Local Government Code; or
- (6) a workers' compensation insurance policy.

 Added by Acts 2013, 83rd Leg., R.S., Ch. 1328 (S.B. 644), Sec. 1, eff. September 1, 2013.

Redesignated from Insurance Code, Section 1369.253 by Acts 2015, 84th Leg., R.S., Ch. 1236 (S.B. 1296), Sec. 21.001(38), eff. September 1, 2015.

Amended by:

Acts 2015, 84th Leg., R.S., Ch. 1236 (S.B. 1296), Sec. 21.002(14), eff. September 1, 2015.

- Sec. 1369.304. STANDARD FORM. (a) The commissioner by rule shall:
- (1) prescribe a single, standard form for requesting prior authorization of prescription drug benefits;
- (2) require a health benefit plan issuer or the agent of the health benefit plan issuer that manages or administers

prescription drug benefits to use the form for any prior authorization of prescription drug benefits required by the plan;

- (3) require that the department and a health benefit plan issuer or the agent of the health benefit plan issuer that manages or administers prescription drug benefits make the form available electronically on the website of:
 - (A) the department;
 - (B) the health benefit plan issuer; and
- (C) the agent of the health benefit plan issuer;
- (4) establish penalties for failure to accept the form and acknowledge receipt of the form as required by commissioner rule.
- (b) Not later than the second anniversary of the date national standards for electronic prior authorization of benefits are adopted, a health benefit plan issuer or the agent of the health benefit plan issuer that manages or administers prescription drug benefits shall exchange prior authorization requests electronically with a prescribing provider who has e-prescribing capability and who initiates a request electronically.
- (c) In prescribing a form under this section, the commissioner shall:
- (1) develop the form with input from the advisory committee on uniform prior authorization forms established under Section 1369.305; and
 - (2) take into consideration:

eff. September 1, 2013.

- (A) any form for requesting prior authorization of benefits that is widely used in this state or any form currently used by the department;
- (B) request forms for prior authorization of benefits established by the federal Centers for Medicare and Medicaid Services; and
- (C) national standards, or draft standards, pertaining to electronic prior authorization of benefits.

 Added by Acts 2013, 83rd Leg., R.S., Ch. 1328 (S.B. 644), Sec. 1,

Redesignated from Insurance Code, Section 1369.254 by Acts 2015,

84th Leg., R.S., Ch. 1236 (S.B. 1296), Sec. 21.001(38), eff. September 1, 2015.

Amended by:

Acts 2015, 84th Leg., R.S., Ch. 1236 (S.B. 1296), Sec. 21.002(15), eff. September 1, 2015.

Sec. 1369.305. ADVISORY COMMITTEE ON UNIFORM PRIOR AUTHORIZATION FORMS. (a) The commissioner shall appoint a committee to advise the commissioner on the technical, operational, and practical aspects of developing the single, standard prior authorization form required under Section 1369.304 for requesting prior authorization of prescription drug benefits.

- (b) The advisory committee shall determine the following:
- (1) a single standard form for requesting prior authorization of prescription drug benefits;
- (2) the length of the standard prior authorization form;
- (3) the length of time allowed for acknowledgement of receipt of the form by the health benefit plan issuer or the agent of the health benefit plan issuer that manages or administers prescription drug benefits;
 - (4) the acceptable methods to acknowledge receipt; and
- (5) the penalty imposed on the health benefit plan issuer or the agent of the health benefit plan issuer that manages or administers prescription drug benefits for failure to acknowledge receipt of the form.
- (c) The commissioner shall consult the advisory committee with respect to any rule relating to a subject described by Section 1369.304 or this section before adopting the rule and may consult the committee as needed with respect to a subsequent amendment of an adopted rule.
- (d) Not later than the second anniversary of the final approval of the standard prior authorization form, and every two years subsequently, the commissioner shall convene the advisory committee to review the standard prior authorization form, examine the form's effectiveness and impact on patient safety, and determine whether changes are needed.

- (e) The advisory committee shall be composed of the commissioner of insurance or the commissioner's designee, the executive commissioner of the Health and Human Services Commission or the executive commissioner's designee, and an equal number of members from each of the following groups:
 - (1) physicians;
 - (2) other prescribing health care providers;
 - (3) consumers experienced with prior authorizations;
 - (4) hospitals;
 - (5) pharmacists;
 - (6) specialty pharmacies;
 - (7) pharmacy benefit managers;
 - (8) specialty drug distributors;
- (9) health benefit plan issuers for the Texas Health Insurance Pool established under Chapter 1506;
 - (10) health benefit plan issuers; and
 - (11) health benefit plan networks of providers.
- (f) A member of the advisory committee serves without compensation.
- (g) Section 39.003(a) of this code and Chapter 2110, Government Code, do not apply to the advisory committee.

Added by Acts 2013, 83rd Leg., R.S., Ch. 1328 (S.B. 644), Sec. 1, eff. September 1, 2013.

Redesignated from Insurance Code, Section 1369.255 by Acts 2015, 84th Leg., R.S., Ch. 1236 (S.B. 1296), Sec. 21.001(38), eff. September 1, 2015.

Amended by:

Acts 2015, 84th Leg., R.S., Ch. 1236 (S.B. 1296), Sec. 21.002(16), eff. September 1, 2015.

Sec. 1369.306. FAILURE TO USE OR ACKNOWLEDGE STANDARD FORM. If a health benefit plan issuer or the agent of the health benefit plan issuer that manages or administers prescription drug benefits fails to use or accept the form prescribed under this subchapter or fails to acknowledge the receipt of a completed form submitted by a prescribing provider, as required by commissioner rule, the health benefit plan issuer or the agent of the health

benefit plan issuer is subject to the penalties established by the commissioner.

Added by Acts 2013, 83rd Leg., R.S., Ch. 1328 (S.B. 644), Sec. 1, eff. September 1, 2013.

Redesignated from Insurance Code, Section 1369.256 by Acts 2015, 84th Leg., R.S., Ch. 1236 (S.B. 1296), Sec. 21.001(38), eff. September 1, 2015.

SUBCHAPTER H. MAXIMUM ALLOWABLE COST

Sec. 1369.351. DEFINITIONS. In this subchapter:

- (1) "Health benefit plan" has the meaning assigned by Section 1369.251, as added by Chapter 915 (H.B. 1358), Acts of the 83rd Legislature, Regular Session, 2013.
- (2) "Pharmacy benefit manager" has the meaning assigned by Section 4151.151.

Added by Acts 2015, 84th Leg., R.S., Ch. 596 (S.B. 332), Sec. 1, eff. January 1, 2016.

- Sec. 1369.352. CERTAIN BENEFITS EXCLUDED. This subchapter does not apply to maximum allowable costs for pharmacy benefits provided under:
- (1) a Medicaid managed care program operated under Chapter 533, Government Code;
- (2) a Medicaid program operated under Chapter 32, Human Resources Code;
- (3) the child health plan program under Chapter 62, Health and Safety Code;
- (4) the health benefits plan for children under Chapter 63, Health and Safety Code;
- (5) a health benefit plan issued under Chapter 1551, 1575, 1579, or 1601; or
- (6) a workers' compensation insurance policy or other form of providing medical benefits under Title 5, Labor Code.

 Added by Acts 2015, 84th Leg., R.S., Ch. 596 (S.B. 332), Sec. 1, eff. January 1, 2016.

Sec. 1369.353. CRITERIA FOR DRUGS ON MAXIMUM ALLOWABLE COST LISTS. A health benefit plan issuer or pharmacy benefit manager may not include a drug on a maximum allowable cost list unless:

(1) the drug:

- (A) has an "A" or "B" rating in the most recent version of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book; or
- (B) is rated "NR" or "NA" or has a similar rating by a nationally recognized reference; and

(2) the drug is:

- (A) generally available for purchase by pharmacists and pharmacies in this state from a national or regional wholesaler; and
- (B) not obsolete.

 Added by Acts 2015, 84th Leg., R.S., Ch. 596 (S.B. 332), Sec. 1, eff. January 1, 2016.
- Sec. 1369.354. FORMULATION OF MAXIMUM ALLOWABLE COSTS; DISCLOSURES. (a) In formulating the maximum allowable cost price for a drug, a health benefit plan issuer or pharmacy benefit manager may only use the price of that drug and any drug listed as therapeutically equivalent to that drug in the most recent version of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.
- (b) Notwithstanding Subsection (a), if a therapeutically equivalent generic drug is unavailable or has limited market presence, a health benefit plan issuer or pharmacy benefit manager may place on a maximum allowable cost list a drug that has:
- (1) a "B" rating in the most recent version of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book; or
- (2) an "NR" or "NA" rating or a similar rating by a nationally recognized reference.
 - (c) A health benefit plan issuer or pharmacy benefit manager

must, in accordance with Subsection (d), disclose to a pharmacist or pharmacy the sources of the pricing data used in formulating maximum allowable cost prices.

- (d) The information described by Subsection (c) must be disclosed:
- (1) on the date the health benefit plan issuer or pharmacy benefit manager enters into the contract with the pharmacist or pharmacy; and
- (2) after that contract date, on the request of the pharmacist or pharmacy.

Added by Acts 2015, 84th Leg., R.S., Ch. 596 (S.B. 332), Sec. 1, eff. January 1, 2016.

Sec. 1369.355. UPDATES. (a) A health benefit plan issuer or pharmacy benefit manager shall establish a process that will in a timely manner eliminate drugs from maximum allowable cost lists or modify maximum allowable cost prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.

(b) A health benefit plan issuer or pharmacy benefit manager shall review and update maximum allowable cost price information for each drug at least once every seven days to reflect any modification of maximum allowable cost pricing.

Added by Acts 2015, 84th Leg., R.S., Ch. 596 (S.B. 332), Sec. 1, eff. January 1, 2016.

Sec. 1369.356. ACCESS TO MAXIMUM ALLOWABLE COST LISTS. A health benefit plan issuer or pharmacy benefit manager must provide to each pharmacist or pharmacy under contract with the health benefit plan issuer or pharmacy benefit manager a process to readily access the maximum allowable cost list that applies to the pharmacist or pharmacy.

Added by Acts 2015, 84th Leg., R.S., Ch. 596 (S.B. 332), Sec. 1, eff. January 1, 2016.

Sec. 1369.357. APPEAL FROM MAXIMUM ALLOWABLE COST PRICE DETERMINATION. (a) A health benefit plan issuer or pharmacy

benefit manager must provide in the contract with each pharmacist or pharmacy a procedure for the pharmacist or pharmacy to appeal a maximum allowable cost price of a drug on or before the 10th day after the date a pharmacy benefit claim for the drug is made.

- (b) The health benefit plan issuer or pharmacy benefit manager shall respond to an appeal described by Subsection (a) in a documented communication not later than the 10th day after the date the appeal is received by the health benefit plan issuer or pharmacy benefit manager.
- (c) If the appeal is successful, the health benefit plan issuer or pharmacy benefit manager shall:
- (1) adjust the maximum allowable cost price that is the subject of the appeal effective on the day after the date the appeal is decided;
- (2) apply the adjusted maximum allowable cost price to all similarly situated pharmacists and pharmacies as determined by the health benefit plan issuer or pharmacy benefit manager; and
- (3) allow the pharmacist or pharmacy that succeeded in the appeal to reverse and rebill the pharmacy benefit claim giving rise to the appeal.
- (d) If the appeal is not successful, the health benefit plan issuer or pharmacy benefit manager shall disclose to the pharmacist or pharmacy:
 - (1) each reason the appeal is denied; and
- (2) the national drug code number from the national or regional wholesalers from which the drug is generally available for purchase by pharmacists and pharmacies in this state at the maximum allowable cost price that is the subject of the appeal.

Added by Acts 2015, 84th Leg., R.S., Ch. 596 (S.B. 332), Sec. 1, eff. January 1, 2016.

Sec. 1369.358. CONFIDENTIALITY OF MAXIMUM ALLOWABLE COST LIST. A maximum allowable cost list that applies to a pharmacist or pharmacy and is maintained by a health benefit plan issuer or pharmacy benefit manager is confidential. This section may not be construed to alter a health benefit plan issuer's or pharmacy benefit manager's obligations under Section 1369.356.

Added by Acts 2015, 84th Leg., R.S., Ch. 596 (S.B. 332), Sec. 1, eff. January 1, 2016.

Sec. 1369.359. WAIVER PROHIBITED. The provisions of this subchapter may not be waived, voided, or nullified by contract.

Added by Acts 2015, 84th Leg., R.S., Ch. 596 (S.B. 332), Sec. 1, eff. January 1, 2016.

Sec. 1369.360. REMEDIES NOT EXCLUSIVE. This subchapter may not be construed to waive a remedy at law available to a pharmacist or pharmacy.

Added by Acts 2015, 84th Leg., R.S., Ch. 596 (S.B. 332), Sec. 1, eff. January 1, 2016.

Sec. 1369.361. ENFORCEMENT. The commissioner shall enforce this subchapter.

Added by Acts 2015, 84th Leg., R.S., Ch. 596 (S.B. 332), Sec. 1, eff. January 1, 2016.

Sec. 1369.362. LEGISLATIVE DECLARATION. It is the intent of the legislature that, except with respect to the benefits excluded under Section 1369.352, the requirements contained in this subchapter apply to all health benefit plan issuers and pharmacy benefit managers unless otherwise prohibited by federal law.

Added by Acts 2015, 84th Leg., R.S., Ch. 596 (S.B. 332), Sec. 1, eff. January 1, 2016.

SUBCHAPTER I. PHARMACY BENEFIT CLAIM ADJUDICATION

Sec. 1369.401. DEFINITION. In this subchapter, "pharmacy benefit manager" has the meaning assigned by Section 4151.151.

Added by Acts 2015, 84th Leg., R.S., Ch. 10 (S.B. 94), Sec. 1, eff. September 1, 2015.

Sec. 1369.402. CERTAIN FEES PROHIBITED. A health benefit plan issuer or a pharmacy benefit manager may not directly or indirectly charge or hold a pharmacist or pharmacy responsible for

a fee for any step of or component or mechanism related to the claim adjudication process, including:

- (1) the adjudication of a pharmacy benefit claim;
- (2) the processing or transmission of a pharmacy benefit claim;
- (3) the development or management of a claim processing or adjudication network; or
- (4) participation in a claim processing or adjudication network.

Added by Acts 2015, 84th Leg., R.S., Ch. 10 (S.B. 94), Sec. 1, eff. September 1, 2015.

SUBCHAPTER J. COVERAGE RELATED TO PRESCRIPTION DRUG SYNCHRONIZATION

Sec. 1369.451. DEFINITIONS. In this subchapter:

- (1) "Cost-sharing amount" includes an amount charged for a deductible, coinsurance, or copayment.
- (2) "Health care provider" means a person who provides health care services under a license, certificate, registration, or other similar evidence of regulation issued by this or another state of the United States.
- (3) "Physician" means an individual licensed to practice medicine in this or another state of the United States.

 Added by Acts 2017, 85th Leg., R.S., Ch. 1007 (H.B. 1296), Sec. 1, eff. September 1, 2017.
- Sec. 1369.452. APPLICABILITY OF SUBCHAPTER. (a) This subchapter applies only to a health benefit plan that provides benefits for medical or surgical expenses incurred as a result of a health condition, accident, or sickness, including an individual, group, blanket, or franchise insurance policy or insurance agreement, a group hospital service contract, or an individual or group evidence of coverage or similar coverage document that is offered by:
 - (1) an insurance company;
 - (2) a group hospital service corporation operating

- under Chapter 842;
- (3) a health maintenance organization operating under Chapter 843;
- (4) an approved nonprofit health corporation that holds a certificate of authority under Chapter 844;
- (5) a multiple employer welfare arrangement that holds a certificate of authority under Chapter 846;
- (6) a stipulated premium company operating under Chapter 884;
- (7) a fraternal benefit society operating under Chapter 885; or
 - (8) an exchange operating under Chapter 942.
- (b) This subchapter applies to group health coverage made available by a school district in accordance with Section 22.004, Education Code.
- (c) Notwithstanding any provision in Chapter 1551, 1575, 1579, or 1601 or any other law, this subchapter applies to health benefit plan coverage provided under:
 - (1) Chapter 1551;
 - (2) Chapter 1575;
 - (3) Chapter 1579; and
 - (4) Chapter 1601.
- (d) Notwithstanding Section 1501.251 or any other law, this subchapter applies to coverage under a small employer health benefit plan subject to Chapter 1501.
- (e) This subchapter applies to a standard health benefit plan issued under Chapter 1507.
- (f) To the extent allowed by federal law, the child health plan program operated under Chapter 62, Health and Safety Code, and the state Medicaid program, including the Medicaid managed care program operated under Chapter 533, Government Code, shall provide the coverage required under this subchapter to a recipient.

 Added by Acts 2017, 85th Leg., R.S., Ch. 1007 (H.B. 1296), Sec. 1, eff. September 1, 2017.
- Sec. 1369.453. APPLICABILITY TO CERTAIN MEDICATIONS. This subchapter applies with respect to only a medication that:

- (1) is covered by the enrollee's health benefit plan;
- (2) meets the prior authorization criteria specifically applicable to the medication under the health benefit plan on the date the request for synchronization is made;
- (3) is used for treatment and management of a chronic illness, as that term is defined by Section 1369.456;
 - (4) may be prescribed with refills;
- (5) is a formulation that can be effectively dispensed in accordance with the medication synchronization plan described by Section 1369.456; and
- (6) is not, according to the schedules established by the commissioner of the Department of State Health Services under Chapter 481, Health and Safety Code:
 - (A) a Schedule II controlled substance; or
- (B) a Schedule III controlled substance containing hydrocodone.

Added by Acts 2017, 85th Leg., R.S., Ch. 1007 (H.B. 1296), Sec. 1, eff. September 1, 2017.

- Sec. 1369.454. PRORATION OF COST-SHARING AMOUNT REQUIRED.

 (a) A health benefit plan that provides benefits for prescription drugs shall prorate any cost-sharing amount charged for a partial supply of a prescription drug if:
- (1) the pharmacy or the enrollee's prescribing physician or health care provider notifies the health benefit plan that:
- (A) the quantity dispensed is to synchronize the dates that the pharmacy dispenses the enrollee's prescription drugs; and
- (B) the synchronization of the dates is in the best interest of the enrollee; and
 - (2) the enrollee agrees to the synchronization.
- (b) The proration described by Subsection (a) must be based on the number of days' supply of the drug actually dispensed.

 Added by Acts 2017, 85th Leg., R.S., Ch. 1007 (H.B. 1296), Sec. 1, eff. September 1, 2017.

- Sec. 1369.455. PRORATION OF DISPENSING FEE PROHIBITED. A health benefit plan that prorates a cost-sharing amount as required by Section 1369.454 may not prorate the fee paid to the pharmacy for dispensing the drug for which the cost-sharing amount was prorated. Added by Acts 2017, 85th Leg., R.S., Ch. 1007 (H.B. 1296), Sec. 1, eff. September 1, 2017.
- Sec. 1369.456. IMPLEMENTATION OF CERTAIN MEDICATION SYNCHRONIZATION PLANS. (a) For the purposes of this section:
- (1) "Chronic illness" means an illness or physical condition that may be:
- (A) reasonably expected to continue for an uninterrupted period of at least three months; and
- (2) "Medication synchronization plan" means a plan established for the purpose of synchronizing the filling or refilling of multiple prescriptions.
- (b) A health benefit plan shall establish a process through which the following parties may jointly approve a medication synchronization plan for medication to treat an enrollee's chronic illness:
 - (1) the health benefit plan;
 - (2) the enrollee;
- $\hbox{(3)} \quad \hbox{the prescribing physician or health care provider;} \\$
 - (4) a pharmacist.
- (c) A health benefit plan shall provide coverage for a medication dispensed in accordance with the dates established in the medication synchronization plan described by Subsection (b).
- (d) A health benefit plan shall establish a process that allows a pharmacist or pharmacy to override the health benefit plan's denial of coverage for a medication described by Subsection (b).
- (e) A health benefit plan shall allow a pharmacist or pharmacy to override the health benefit plan's denial of coverage through the process described by Subsection (d), and the health

benefit plan shall provide coverage for the medication if:

- (1) the prescription for the medication is being refilled in accordance with the medication synchronization plan described by Subsection (b); and
- (2) the reason for the denial is that the prescription is being refilled before the date established by the plan's general prescription refill guidelines.

Added by Acts 2017, 85th Leg., R.S., Ch. 1007 (H.B. 1296), Sec. 1, eff. September 1, 2017.

SUBCHAPTER K. PRESCRIPTION DRUG COST TRANSPARENCY

Sec. 1369.501. DEFINITIONS. In this subchapter:

- (1) "Animal health product" means a medical product approved and licensed for use in animal or veterinary medicine, including a pharmaceutical, a biologic, an insecticide, and a parasiticide.
- (2) "Health benefit plan" means an individual, blanket, or group plan, policy, or contract for health care services issued or delivered by a health benefit plan issuer in this state.
- (3) "Health benefit plan issuer" means an insurance company, a health maintenance organization, or a hospital and medical service corporation.
- (4) "Pharmaceutical drug manufacturer" means a person engaged in the business of producing, preparing, propagating, compounding, converting, processing, packaging, labeling, or distributing a prescription drug. The term does not include a wholesale distributor or retailer of prescription drugs or a pharmacist licensed under Subtitle J, Title 3, Occupations Code.
- (5) "Pharmacy benefit manager" has the meaning assigned by Section 4151.151.
- (6) "Prescription drug" has the meaning assigned by Section 551.003, Occupations Code, except that the term "prescription drug" does not include a device or an animal health product.
 - (7) "Rebate" means a discount or concession that

affects the price of a prescription drug to a pharmacy benefit manager or health benefit plan issuer for a prescription drug manufactured by the pharmaceutical drug manufacturer.

- (8) "Specialty drug" means a prescription drug covered under Medicare Part D that exceeds the specialty tier cost threshold established by the Centers for Medicare and Medicaid Services.
- (9) "Utilization management" means a set of formal techniques designed to monitor the use of, or evaluate the medical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings.

Added by Acts 2019, 86th Leg., R.S., Ch. 1291 (H.B. 2536), Sec. 2, eff. September 1, 2019.

The following section was amended by the 87th Legislature. Pending publication of the current statutes, see H.B. 1033, 87th

Legislature, Regular Session, for amendments affecting the following section.

- Sec. 1369.502. PHARMACY BENEFIT MANAGER INFORMATION.

 (a) Not later than February 1 of each year, each pharmacy benefit manager shall file a report with the commissioner. The report must state for the immediately preceding calendar year:
- (1) the aggregated rebates, fees, price protection payments, and any other payments collected from pharmaceutical drug manufacturers; and
- (2) the aggregated dollar amount of rebates, fees, price protection payments, and any other payments collected from pharmaceutical drug manufacturers that were:
 - (A) passed to:
 - (i) health benefit plan issuers; or
- (ii) enrollees at the point of sale of a
 prescription drug; or
- (B) retained as revenue by the pharmacy benefit manager.
- (a-1) Notwithstanding Subsection (a), the report due not later than February 1, 2020, under that subsection must state the required information for the immediately preceding three calendar

years in addition to stating the required information for the preceding calendar year. This subsection expires September 1, 2021.

- (b) A report submitted by a pharmacy benefit manager may not disclose the identity of a specific health benefit plan or enrollee, the price charged for a specific prescription drug or class of prescription drugs, or the amount of any rebate or fee provided for a specific prescription drug or class of prescription drugs.
- (c) Not later than May 1 of each year, the commissioner shall publish the aggregated data from all reports for that year required by this section in an appropriate location on the department's Internet website. The combined aggregated data from the reports must be published in a manner that does not disclose or tend to disclose proprietary or confidential information of any pharmacy benefit manager.

Added by Acts 2019, 86th Leg., R.S., Ch. 1291 (H.B. 2536), Sec. 2, eff. September 1, 2019.

The following section was amended by the 87th Legislature. Pending publication of the current statutes, see H.B. 1033, 87th Legislature, Regular Session, for amendments affecting the following section.

- Sec. 1369.503. HEALTH BENEFIT PLAN ISSUER INFORMATION.

 (a) Not later than February 1 of each year, each health benefit plan issuer shall submit to the commissioner a report that states for the immediately preceding calendar year:
- (1) the names of the 25 most frequently prescribed prescription drugs across all plans;
- (2) the percent increase in annual net spending for prescription drugs across all plans;
- (3) the percent increase in premiums that were attributable to prescription drugs across all plans;
- (4) the percentage of specialty drugs with utilization management requirements across all plans; and
- (5) the premium reductions that were attributable to specialty drug utilization management.

- (b) A report submitted by a health benefit plan issuer may not disclose the identity of a specific health benefit plan or the price charged for a specific prescription drug or class of prescription drugs.
- (c) Not later than May 1 of each year, the commissioner shall publish the aggregated data from all reports for that year required by this section in an appropriate location on the department's Internet website. The combined aggregated data from the reports must be published in a manner that does not disclose or tend to disclose proprietary or confidential information of any health benefit plan issuer.

Added by Acts 2019, 86th Leg., R.S., Ch. 1291 (H.B. 2536), Sec. 2, eff. September 1, 2019.

Sec. 1369.504. RULES. The commissioner may adopt rules to implement this subchapter.

Added by Acts 2019, 86th Leg., R.S., Ch. 1291 (H.B. 2536), Sec. 2, eff. September 1, 2019.